DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1426]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Emergency Health Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Emergency Health Surveys

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i)), FDA is authorized to require: (1) Manufacturers to report medical-device-related deaths, serious injuries, and malfunctions; and (2) user facilities to report device-related deaths directly to FDA

and to manufacturers, and to report serious injuries to the manufacturer. Section 522 of the act (21 U.S.C. 360(l)) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 903(b)(2) of the act (21 U.S.C. 393(b)(2)) authorizes the Commissioner of Food and Drugs (the Commissioner) to implement general powers (including conducting research) to effectively carry out the mission of FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with medical device usage that are not foreseen or apparent during the premarket notification and review process. Currently FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch Reporting Systems using FDA Forms 3500 and 3500A (OMB Control No. 0910–0281).

FDA is seeking OMB clearance to collect information via a series of surveys, thus implementing section 705(b) of the act and the Commissioner's authority as specified in section 903(b)(2) of the act. Participation in these surveys will be voluntary. This request covers emergency health surveys for general type medical facilities; specialized medical facilities (those known for cardiac surgery, obstetrics/gynecology services, pediatric services, etc.); and health professionals, but more typically risk managers working in medical facilities.

FDA will use the information gathered from these surveys to quickly obtain vital information from the appropriate clinical sources so that FDA may take appropriate public health or regulatory action. FDA projects 10 emergency health surveys per year with a sample of between 50 and 200 respondents per survey.

In the **Federal Register** of August 3, 2000 (65 FR 47734), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
200	10 (maximum)	2,000	2	4,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the maximum sample size per questionnaire that FDA could analyze in a timely manner. The annual frequency of respondent was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only one time per year, while another respondent may be contacted several times, depending on the medical device under evaluation. It is estimated that, given the expected type

of issues that will be addressed by the surveys, at a maximum it will take 2 hours for a respondent to gather the requested information and fill in the answers.

Dated: October 23, 2000

Margaret M. Dotzel,
Associate Commissioner for Policy.

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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